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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,023	04/02/2004	Salvatore V. Pizzo	5405-304	2746

20792 7590 12/04/2008

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
12/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,023	PIZZO ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16-20 and 28* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16-19 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/03/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-13, 15 and 21-27 are cancelled. Claim 28 is added. Claims 14, 16-20 and 28 are pending. Claim 20 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/04/2006. Claims 14, 16-19 and 28 are under examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 14, 16-19 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosok et al.[1] in view of Lenney et al.,[2] as evidenced by Hood et al.[3]

In response tot eh rejection, Applicant argues that Rosok et al. is non-analogous to the claimed invention for the teachings of Rosok et al. is directed to passive immunity, whereas, the claimed invention is directed at active immunity. Applicant also argues that the claimed invention is not obvious over the teachings of Rosok et al. and Hood et al.., because the teachings of Hood et al., is flawed. That is, Applicant argues that the references cannot be combined without destroying the functioning of Rosok et

[1] Rosok et al. U.S. Patent No. 4834976, published May 30, 1989.
[2] Lenney et al. Antimicrobial action of Compound 48/80 against protozoa, bacteria and fungi. Journal of Pharmaceutical Sciences. May 1977, Vol. 66, No. 5, 702-705

al. Applicant also argues that Hood et al. is not directed at passive immunity. Lastly, Applicant argues that Lenney et al. failed to suggest the use of Compound 48/80 as an adjuvant. Applicant also argues that Lenney et al. is silent regarding immunogens, combining Compound 48/80 with other agents or using Compound 48/80 to raise a therapeutic immune response in a subject.

Applicant's arguments have been considered, however, it is not found persuasive. Contrary to Applicant's assertion, Rosok et al. is not non-analogous to the claimed invention. The claimed invention is directed at the simultaneous administration of an immunogen and compound 48/80 with a pharmaceutical carrier to a subject to induce an immune response. In the instant case, Rosok et al., in view of Lenney et al. render the simultaneous administration of an immunogen and compound 48/80 with a pharmaceutical carrier to a subject to induce an immune response obvious for the reason(s) set forth in the office action.

In response to applicant's argument that there is no suggestion provided by Lenney et al. to combine the references (Lenney et al. with Rosok et al.), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Lenney et al. teaches the use of

[3] Hood et al. Immunology, 2nd Edition. The Benjamin/Cummings Publishing Company, Inc., California, 1984, 371-373.

Compound 48/80 as an antimicrobial agent. At the time the invention was made, Rosok et al. teaches the administration of a composition comprising an immunogen and an antimicrobial agent with a pharmaceutical carrier. Hence, at the time the invention was made, to use Compound 48/80 as the antimicrobial agent in the composition of Rosok et al. Hence, contrary to Applicant's assertion that there is not motivation or suggestion to combine, such is detailed in the rejection and the references.

Regarding Applicant's asserting that the claimed invention is not obvious over the teachings of Rosok et al. and Hood et al., Applicant is reminded that the rejection is over Rosok et al., in view of Lenney et al. Hood et al. is cited to evidence that the administration of the composition of Rosok et al. would inherently induce an immune response. Additionally, Applicant's request for complete teachings of Hood et al. has been noted, however, a copy cannot readily be ascertained. However, Applicant should note the obviousness rejection is not made in view of Hood et al., any arguments directed against Hood et al. probably wouldn't be sufficient to overcome the rejection. Moreover, the administration of an antibody would necessarily result in the induction of an immune response.

As previously indicated in the office action mailed 05/08/2008, in response to the rejection, Applicant argues that Rosok et al. does not teach a composition comprising an immunogen and an antimicrobial agent. Rather, Applicant argues that Rosok et al. teaches of composition comprising antibodies and an antimicrobial agent, and its use for the treatment or prophylaxis of *P. aeruginosa* infection with the administration of the composition.

Applicant's arguments have been considered, however, it is not found persuasive. While the entire disclosure of Rosok et al. is directed to antibodies, however, it should be noted that Rosok et al. used the antibodies as an antigen to induce an immune response for the treatment or prophylaxis of *P. aeruginosa* infection with the administration of the composition comprising antibodies and an antimicrobial agent. In the context of cited claim 17 of Rosok et al., Rosok et al. suggested using the antibodies as an antigen. And per Applicant's disclosure, the terms immunogen and antigen are interchangeable. The use of antibodies as antigens is well known in the art at the time the invention was filed. This is evidenced by Hood et al. Hood et al. teaches that antibodies carry new antigenic determinants, called idiotopes, which can behave as antigens to trigger an immune response, wherein the antibodies induced are called anti-idiotype antibodies. In the instant case, Rosok et al. administered the antibodies as antigens to induce an immune response that leads to the treatment or prophylaxis of *P. aeruginosa* infection, wherein the immune response induced would necessarily include the production anti-idiotype antibodies, which indicates a humoral immune response to provide treatment or prophylaxis of *P. aeruginosa* infection. Thus, while Applicant's arguments have been considered, none of the arguments are found persuasive.

In addition to above, Applicant argues that Lenney et al. is silent on immunogens, combining Compound 48/80 with other agents or using Compound 48/80 to raise a therapeutic immune response in the subject. Applicant also argues that combined, Rosok et al. and Lenney et al. fail to disclose every limitation of the claimed invention.

Applicant's arguments have been considered, however, it is not found persuasive. Had Lenney et al. discloses all the elements of the claimed invention, the

cited reference would have been cited as anticipating the claimed invention in an anticipatory rejection. Instead, the reference is cited in view of Rosok et al. as rendering the claimed invention obvious. Together the reference combined, teach every element of the claimed invention. As discussed in the previous office action, and reiterated below, while Rosok et al. teaches a composition comprising an immunogen and antimicrobial agent with a pharmaceutical carrier, Rosok et al. does not specify the use of Compound 48/80 as an antimicrobial agent. However, at the time the invention was made, Lenney et al. teaches the use of Compound 48/80 as an antimicrobial agent. Hence, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use compound 48/80 as the antimicrobial agent in the composition of Rosok et al. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to inhibit microbial growth. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the Compound 48/80 is an antimicrobial agent. Thus, contrary to Applicant's arguments, Rosok et al. and Lenney et al. combined, teach every element of the claimed invention, thereby rendering the claimed invention obvious. Hence, while Applicant's arguments have been considered, they are not found persuasive.

The claims are directed at the simultaneous administration of an immunogen and compound 48/80 with a pharmaceutical carrier to a subject to induce an immune response. Claim 16, which depends on claim 14, requires that the administration be parenteral. Claim 17, which depends on claim 14, requires the immune response to be a prophylactic immune response to bacterial or viral infection. Claim 18, which depends

on claim 14, requires the immune response to be therapeutic. Claim 19, which depends on claim 14, requires the immune response to comprise a humoral immune response. Newly added claim 28, which depends on claim 14, requires that the administration method be mucosal.

Rosok et al. teaches a composition comprising an immunogen and antimicrobial agent with a pharmaceutical carrier. [Claim 17, columns 28-29, in particular.] Rosok et al. also teaches the administration of the composition to induce a prophylactic and therapeutic immune response against *P. aeruginosa* infection. [Claim 22, column 30, in particular.]

Rosok et al. does not specify the use of Compound 48/80 as an antimicrobial agent.

However, at the time the invention was made, Lenney et al. teaches the use of Compound 48/80 as an antimicrobial agent.

Hence, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use compound 48/80 as the antimicrobial agent in the composition of Rosok et al. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so inhibit microbial growth. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the Compound 48/80 is an antimicrobial agent.

Additionally, Rosok et al. teaches that the composition may be administered parenterally. [Lines 57-65, column 8, in particular.] Thus, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to

administer the composition parenterally. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so facilitate the administration of the composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because parental administration is routinely practiced in the art.

While neither Rosok et al. nor Lenney et al. teach mucosal administration methods, however, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to use alternative methods of administration, including mucosal or intranasal administration methods. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to facilitate the delivery of the pharmaceutical composition rendered obvious by Rosok et al. and Lenney et al. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of alternative administration methods are routinely practiced in the art.

Conclusion

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./